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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,997	02/02/2004	Claus Riehle	PO-8010/LeA 36,342	2148
157	7590 05/02/2006		EXAMINER	
BAYER MATERIAL SCIENCE LLC			SUNG, CHRISTINE	
100 BAYER ROAD PITTSBURGH, PA 15205			ART UNIT	PAPER NUMBER
			2884	
			DATE MAILED: 05/02/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

•			H			
	Application No.	Applicant(s)				
	10/769,997	RIEHLE ET AL.				
Office Action Summary	Examiner	Art Unit	٦			
	Christine Sung	2884				
The MAILING DATE of this communication appeariod for Reply	pears on the cover sheet with the	correspondence address				
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING [ - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statu. Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICATION  .136(a). In no event, however, may a reply be to some standard will expire SIX (6) MONTHS from the cause the application to become ABANDON	N. imely filed in the mailing date of this communication. ED (35 U.S.C. § 133).				
Status		•				
1)⊠ Responsive to communication(s) filed on <u>03 i</u>	March 2006.					
2a) This action is <b>FINAL</b> . 2b) ☑ This	This action is FINAL. 2b) This action is non-final.					
3) Since this application is in condition for allows						
closed in accordance with the practice under	Ex parte Quayle, 1935 C.D. 11, 4	153 O.G. 213.				
Disposition of Claims						
4)⊠ Claim(s) <u>1-24</u> is/are pending in the application	n.					
4a) Of the above claim(s) is/are withdra						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-24</u> is/are rejected.	6)⊠ Claim(s) <u>1-24</u> is/are rejected.					
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/	or election requirement.					
Application Papers						
9) The specification is objected to by the Examin	ner.					
10) The drawing(s) filed on 02 February 2004 is/a	re: a)⊠ accepted or b)⊡ object	ed to by the Examiner.				
Applicant may not request that any objection to the	e drawing(s) be held in abeyance. S	ee 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the corre						
11)☐ The oath or declaration is objected to by the E	Examiner. Note the attached Office	e Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12)⊠ Acknowledgment is made of a claim for foreig a)⊠ All b)□ Some * c)□ None of:	n priority under 35 U.S.C. § 119(	a)-(d) or (f).				
1. Certified copies of the priority documer	nts have been received.					
2. Certified copies of the priority documer						
<ol><li>Copies of the certified copies of the pri</li></ol>		ved in this National Stage				
application from the International Bure	<b>;</b>					
* See the attached detailed Office action for a lis	st of the certified copies not receive	ved.				
Attachment(s)		·				
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summa Paper No(s)/Mail					
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/0: Paper No(s)/Mail Date		Patent Application (PTO-152)				

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#### Response to Amendment

1. The amendment filed on March 3, 2006 has been accepted and entered.

## Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 4. Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hallinan (US Patent 6,103,934 A) in view of NPL David Firth Reference "Nitration Reactions in the manufacture of Pharmaceutical Intermediates."

Regarding claim 1, Hallinan discloses a process for monitoring and controlling process for monitoring and/or controlling at least one process comprising:

a) measuring spectrometrically (claim 2) an online composition of an acid phase reaction mixture (claim 1),

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b) relaying data from a) to a process control system in order to monitor and to control the production process (claim 1).

Hallinan does not specify that the process for monitoring and controlling is for a nitration reaction. However nitration reactions are used in making many products such as pharmaceutical products and such a process is well known (see attached Firth NPL Reference "Nitration Reactions in the manufacture of Pharmaceutical Intermediates."). One of ordinary skill in the art would be motivated to adapt the process as disclosed by Hallinan with the nitration process as disclosed by Firth in order to efficiently mass produce pharmaceutical products by reducing the processing time.

Regarding claim 2 and 3, Hallinan discloses using an infrared spectrometer (claim 2).

Regarding claim 4, Hallinan discloses using a measuring cell (figure 1, box where IR analyzer is located) is located in a by pass.

Regarding claim 5, Hallinan discloses that the data are based on the spectrometric online measurement and evaluation with a matrix-specific calibration model (column 10, lines 49-53).

Regarding claim 6, Hallinan discloses that the spectrum obtained by online measurement is evaluated with a matrix-specific calibration model based on comparative titration measurements (column 111, lines 56-61).

Regarding claim 7, Hallinan does not specify the exact materials being monitored, however, as stated above, the nitration process, and the subsequent materials used in the reaction process, is known for pharmaceutical manufacture.

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Regarding claims 8-9, Hallinan discloses the a means for performing spectrometric measurements with an evaluating unit (see above and claim1), but does not explicitly state measuring at multiple points of the reaction process. However, one of ordinary skill in the art would be motivated to use multiple measuring points in order to accurately gauge the reaction process, thus increasing the accuracy in monitoring and controlling production of the desired product, and reducing excess or waste of materials.

Regarding claim 10, Hallinan discloses a product capable of automatically implementing the steps of:

- a) evaluating data obtained by a spectrometric examination of an acid phase after reaction to determine the content of acid in the acid phase (claim 1 and 2, using spectrometer to measure acid phase), and
- b) relaying the nitric-acid content data from a) to a regulator to control metering of acid to a reaction mixture (claim 1).

Hallinan does not specify that the process for monitoring and controlling is for a nitration reaction. However nitration reactions are used in making many products such as pharmaceutical products and such a process is well known (see attached Firth NPL Reference "Nitration Reactions in the manufacture of Pharmaceutical Intermediates."). One of ordinary skill in the art would be motivated to adapt the process as disclosed by Hallinan with the nitration process as disclosed by Firth in order to efficiently mass produce pharmaceutical products by reducing the processing time.

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Regarding claim 11, Hallinan discloses that the data are based on the spectrometric online measurement and evaluation with a matrix-specific calibration model (column 10, lines 49-53).

Regarding claim 12, Hallinan discloses that it is designed for automated regulation of the reaction process (claim 1).

Regarding claim 13, Hallinan discloses a facility for monitoring and/or controlling a reaction process comprising:

- a) means for spectrometric examination of an acid phase after a nitration (claim 1), and
- b) regulating means for metering nitric acid into at least one nitrating reactor, the regulating means being designed to regulate metering of acid on the basis of the spectrometric examination. (claim 1 and 2).

Hallinan does not specify that the process for monitoring and controlling is for a nitration reaction. However nitration reactions are used in making many products such as pharmaceutical products and such a process is well known (see attached Firth NPL Reference "Nitration Reactions in the manufacture of Pharmaceutical Intermediates."). One of ordinary skill in the art would be motivated to adapt the process as disclosed by Hallinan with the nitration process as disclosed by Firth in order to efficiently mass produce pharmaceutical products by reducing the processing time.

Regarding claim 14 and 15, Hallinan discloses using an infrared spectrometer (claim 2).

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Regarding claim 16, Hallinan discloses using a measuring cell (figure 1, box where IR analyzer is located) is located in a by pass.

Regarding claims 17 and 20, Hallinan discloses that the spectrum obtained by online measurement is evaluated with a matrix-specific calibration model based on comparative titration measurements (column 111, lines 56-61).

Regarding claims 18 and 21-22, Hallinan discloses the a means for performing spectrometric measurements with an evaluating unit (see above and claim1), but does not explicitly state measuring at multiple points of the reaction process. However, one of ordinary skill in the art would be motivated to use multiple measuring points in order to accurately gauge the reaction process, thus increasing the accuracy in monitoring and controlling production of the desired product, and reducing excess or waste of materials.

Regarding 19 and 23-24, Hallinan discloses having a process control system (figure 1) for the regulating means and a connection of the means for spectrometric examination (IR ANALYZER) to the process control system (Figure 1).

### Response to Arguments

5. Applicant's arguments with respect to claims 1-19 have been considered but are most in view of the new ground(s) of rejection.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Sung whose telephone number is 571-272-2448. The examiner can normally be reached on Monday- Friday 7-3 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Porta can be reached on 571-272-2444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christine Sung Examiner Art Unit 2884

CS

SUPERVISORY PATENT EXAMINER

**TECHNOLOGY CENTER 2800**